Official Title: A feasibility study of a novel mHealth clinical decision support application to enable community health workers to manage hypertension with remote physician supervision

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University of Wisconsin - Madison
Research Participant Information and Consent Form

Study Title: A feasibility study of a novel mHealth clinical decision support application to enable community health workers to manage hypertension with remote physician supervision

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Description of the research
You are invited to participate in a research study to see if community health workers can medically manage high blood pressure (hypertension) in patients from rural communities. This project is important because it will show if community health workers, when aided by mobile applications for clinical decision support (called CommCare), can take care of your high blood pressure. Hypertension is the leading preventable cause of death worldwide. Small improvements in hypertension control could have an effect on the health of many.

You have been asked to take part in this project because you have been told that you have high blood pressure.

The purpose of the research is to see if community health workers (CHW) can manage high blood pressure (hypertension) in patients from rural communities.

This study will include 30 people from rural communities of the San Lucas Toliman municipality (Guatemala). This research will be conducted at your rural clinic or in your home.

What will my participation involve?
If you decide to participate in this research, you will be asked to meet with a community health worker (CHW) at an enrollment visit and monthly thereafter. All study data will be collected using a mobile application running on a smartphone. At enrollment, information on basic demographic information (age, race, sex), past medical history, and current medications will be collected. CHWs will measure blood pressure, height, and weight. Patients will also be asked to complete some surveys. You will be asked about any side effects from your current medications and asked about any signs or symptoms of possible problems from high blood pressure, including ischemic heart disease, cerebrovascular disease, heart failure, and kidney disease. You will have blood drawn and the blood sample will be tested for lipids (fats), serum creatinine, electrolytes, and blood glucose (sugars). Based on the information entered by the CHWs into the mobile application designed for this study, the application will provide advice for the prescription of medications to lower blood pressure and additional medications to reduce cardiovascular risk if indicated, lifestyle changes, and referral to the supervising physician if indicated for potential problems of hypertension. CHWs will then provide you with these treatments assisted by recommendations from the application. Your care plan will be reviewed by a medical doctor each month and the CHWs will also be able to consult with a doctor at any time for advice on your care.

Your participation will last approximately 60-90 minutes per session and will require 7 sessions which will require 7-11 hours in total.

Are there any risks to me?
There are always risks when taking medications. The medications selected for this project are known to be safe and you will be monitored for potential side effects. Your personal and medical information will be collected and there is a risk of a potential loss of your private information. Also, blood pressure measurements and blood draws can cause some discomfort.

Are there any benefits to me?
The primary potential benefit to participants is improved treatment of hypertension and management of cardiovascular risk factors, leading to less risk of cardiovascular events, other complications of uncontrolled hypertension, and mortality.

How will my confidentiality be protected?
Confidentiality means that we will keep your personal information protected. Your information will be protected by having all study visits performed in a private room or, at a minimum, out of earshot of other people. Data will be collected on encrypted, password-protected smartphones using the CommCare application, which is also password protected and encrypted. Study data will be stored on CommCare's secure server, which is HIPAA compliant, secure University of Wisconsin servers, and secure computers in Guatemala. Any hard copies of data containing your personal health information will be stored in locking filing cabinets in controlled-access facilities.

Only approved personnel working on this project will have access to the data.

Protected health information (PHI), is information about your physical or mental health that includes your name or other information that can identify you. To do this study, we will use things you tell the research team about your health.

Your authorization for researchers to use your PHI does not have an end date. However, you can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research. If you take back your authorization, you will not be able to take part in the research study. To take back your authorization, you will need to notify the researchers.

The information collected in this study, including your health information, may be used or shared for future related research.

Whom should I contact if I have questions?
You may ask any questions about the research at any time. If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team or contact the Principal Investigator Sean Duffy MD at 608-354-7930 (phone or WhatsApp).

If you have any questions about your rights as a research patient or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Any participation in research study is completely voluntary. If you decide not to participate or to withdraw from the study, you may do so without penalty.

Your signature indicates that you have read this consent form, had an opportunity to ask any questions about your participation in this research and voluntarily consent to participate. You will receive a copy of this form for your records.

Name of the Participant (please print): _____

Signature: _____

Date: _____

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.